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LAST MONTH AT THE FEDERAL CIRCUIT

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SPOTLIGHT INFO:

On March 6, 2009, the Federal Circuit granted St. Jude Medical, Inc.'s ("St. Jude") petition for en banc rehearing in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, Nos. 07-1296, -1347 (Fed. Cir. Dec. 18, 2008). In 2007, the Supreme Court found that software cannot be considered per se a "component" under 35 U.S.C. § 271(f). *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). In *Cardiac Pacemakers*, the Federal Circuit held that *Microsoft* did not overrule a prior precedential ruling in *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005), that § 271(f) does extend to cover components of a claimed method. St. Jude filed a petition for en banc rehearing on January 21, 2009. The Federal Circuit granted St. Jude's petition and requested that the parties brief the question of whether 35 U.S.C. § 271(f) applies to method claims, as well as product claims. The Court also scheduled oral argument for June 1, 2009.

District Court's Failure to Construe a Disputed Claim Term Considered Harmless Error

Bart A. Gerstenblith

Judges: Bryson, Dyk (dissenting), Prost (author)

[Appealed from W.D. Tex., Judge Furgeson]

In *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*, Nos. 07-1340, -1341, -1342 (Fed. Cir. Feb. 2, 2009), the Federal Circuit affirmed the district court's denial of (1) Defendants Medela, Inc. and Blue Sky Medical Group, Inc.'s ("Blue Sky") motion for JMOL on obviousness; (2) Defendants' alternative motion for a new trial on obviousness; and (3) Plaintiff Kinetic Concepts, Inc.'s motion for JMOL on infringement and its alternative motion for a new trial on infringement. Additionally, the Federal Circuit affirmed the district court's claim construction rulings.

Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences (collectively "KCI") brought suit against Medela AG, Medela, Inc., Richard Weston, and Blue Sky (collectively "Defendants"), alleging infringement of U.S. Patent Nos. 5,636,643 ("the '643 patent") and 5,645,081 ("the '081 patent"), as well as claims of false advertising, unfair competition, and conspiracy. Defendants responded with counterclaims alleging that the asserted patents were invalid and unenforceable. After a six-week trial, the jury found the asserted patents not invalid, unenforceable, or infringed. The jury also found against KCI on its false advertising, unfair competition, and conspiracy claims.

After trial, Defendants filed a motion for JMOL asserting that the claims were invalid as obvious under 35 U.S.C. § 103. In the alternative, Defendants requested a new trial on obviousness. KCI filed its own motion for JMOL on infringement, or in the

alternative, requested a new trial on infringement. The district court denied each of these motions.

Defendants appealed the district court's denial of their JMOL motion on obviousness, arguing that, under a proper claim construction, no reasonable juror could have found that the prior art did not render the asserted patents invalid. In the alternative, Defendants sought a new trial on obviousness, asserting that the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), effected a supervening change in the law that retroactively rendered the jury instructions on obviousness erroneous. Defendants also appealed the district court's determination that several claim terms, including "selected stage of healing," "reduction in bacterial density in the wound by at least 50%," and "screen for prevention of overgrowth," were not indefinite. KCI cross-appealed the district court's denial of its motion for JMOL of infringement, and alternatively requested a new trial on infringement because (1) Defendants presented a legally insufficient "practicing the prior art" defense, (2) compared the accused product to KCI's product, and (3) engaged in "class warfare" before the jury.

The patents-at-issue relate to treating difficult-to-heal wounds by applying suction, which is referred to in the patents as "reduced pressure" or "negative pressure," and encompass both apparatus and method claims. The Federal Circuit primarily focused on four limitations, at least one of which is present in each of the asserted claims: (1) using "reduced" or "negative" pressure to "treat a wound" or "facilitate the healing of a wound"; (2) a "screen" or "screen means" limitations; (3) a limitation requiring treating toward a "selected stage of healing"; and (4) "a reduction in bacterial density in the wound by at least 50%."

With respect to claim construction, the district court first construed the phrase "treating a wound" to mean "giving medical care to an injury," and the

phrase “facilitating the healing of a wound” to mean “facilitating the healing of injuries,” but, in the middle of the trial, the district court vacated its construction of “wound.” As a result, “treating a wound” was construed to mean “giving medical care to a wound.” At trial, the jury was given this construction of “treating a wound” but was not instructed on the meaning of “facilitating the healing of wounds.” Additionally, the district court construed the “screen” limitation to mean “a porous material that applies a counteracting force to granulation tissue to stop growth of granulation tissue above the level of skin surrounding the wound, the porous material being positioned at the wound within the sealing means.”

“Because the jury’s verdict is supported under the proper construction, and because we perceive no danger under the circumstances of this case that the jury may have used an incorrect construction of ‘wound’ that might have prejudiced Defendants, there is no need to remand for a new trial.”
Slip op. at 12.

Defendants alleged several errors in the district court’s treatment of its obviousness contentions (1) that the court’s failure to construe “wound” prevented the jury from properly assessing whether the prior art was within the scope of the asserted claims; (2) that the district court erred by finding that substantial evidence supported the jury’s finding that the patents were not obvious; and (3) that the district court was required to conduct its own independent obviousness analysis and erred by simply reviewing the jury’s verdict for substantial evidence.

First, the Federal Circuit rejected the Defendants’ argument that “wound” should be construed broadly, finding instead that “wound” did not encompass either the “fistulae,” described in one series of prior art references, or the “pus pockets,” described in another series of prior art references. Relying on *Phillips v. AWH Corp.*, 415 F.3d 1393, 1315 (Fed. Cir.

2005) (en banc), the Federal Circuit held that because all of the examples in the specification described skin wounds, a broader interpretation “would thus expand the scope of the claims far beyond anything described in the specification.” Slip op. at 11. The Court further found that the district court’s failure to instruct the jury on the construction of “wound” in this case was harmless. *Id.* at 12. Thus, “[b]ecause the jury’s verdict is supported under the proper construction, and because we perceive no danger under the circumstances of this case that the jury may have used an incorrect construction of ‘wound’ that might have prejudiced Defendants, there is no need to remand for a new trial.” *Id.*

Second, the Federal Circuit found that the jury’s verdict of nonobviousness was supported by substantial evidence. Given the competing expert testimony on the subject, the jury was entitled to judge the credibility of the experts. Additionally, because KCI addressed each of Defendants’ prior art references and provided the jury with a basis for determining that they did not teach or suggest “treating a wound with negative pressure,” a limitation found in every asserted claim, the Court found the evidence sufficient to support the jury’s verdict of nonobviousness.

Third, the Federal Circuit rejected the Defendants’ assertion that the district court erred by not conducting its own obviousness analysis while entertaining their JMOL motion. Given the substantial evidence presented by KCI, the Federal Circuit concluded that the Defendants failed to establish that the asserted claims were obvious as a matter of law.

Additionally, the Federal Circuit rejected the Defendants’ request for a new trial on obviousness because the Court was not persuaded that the instruction on the teaching, suggestion, or motivation requirement for obviousness was “probably responsible for an incorrect verdict,” given the substantial evidence that none of the prior art references “treat wounds with negative pressure.” *Id.* at 16 (citation omitted).

Further, the Federal Circuit rejected the Defendants’ indefiniteness arguments. First, the term “selected stage of healing” was not indefinite because the ‘643 patent specification provided several examples of selected stages of healing that, as explained in a declaration from one of the inventors, a doctor of ordinary skill in the art would understand how the selected stage of healing may vary from wound to wound. Second, “reduction in bacterial density in the wound by at least 50%” was not indefinite in

light of a specific method described in Example 2 of the '643 patent to measure bacterial density. Finally, the term "screen" was not indefinite in light of KCI's explanation that the Defendants mischaracterized the inventors' deposition testimony as definitions of "overgrowth." Accordingly, the Court found that in light of KCI's explanation of the record, it was not persuaded that the term "screen" is "insolubly ambiguous." *Id.* at 19.

Turning to KCI's cross-appeal and motion for JMOL of infringement, the Court first stated that "while Defendants' evidence may not have been overwhelming, it was nonetheless sufficient to support the jury's conclusion." *Id.* at 21. Second, the Federal Circuit found that substantial evidence supported a finding that Blue Sky lacked the necessary intent to establish induced infringement, even though "KCI may be correct that 'practicing the prior art' [as Defendants' had argued] is not a defense to patent infringement." *Id.* at 23 (citation omitted). Finally, the Court denied KCI's motion for a new trial, finding that the district court did not abuse its discretion in denying KCI's motion.

In a dissenting opinion, Judge Dyk stated that the district court's failure to construe the term "wound" was a "clear error." Additionally, Judge Dyk believed the panel majority adopted too narrow a construction for the term. Under Judge Dyk's broader construction of the term, he would have found the claims obvious in light of the prior art.

Under KSR, It Is a Court's Analysis That Must Be Made Explicit, Not Any Teaching in the Prior Art of a Motivation to Combine

Timothy A. Marquart

Judges: Lourie (author), Cleverger, Linn

[Appealed from N.D. Ill., Judge Der-Yeghiayan]

In *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, No. 08-1333 (Fed. Cir. Feb. 9, 2009), the Federal Circuit overturned the district court's SJ on validity and infringement of U.S. Patent No. 6,457,969 ("the '969 patent").

Ball Aerosol and Specialty Container, Inc. ("BASC") owns the '969 patent, which is directed to a candle tin with a removable cover that also acts as a base for the candle holder. Putting the candle tin in the configuration disclosed in the '969 patent, with the

candle holder resting on top of the cover, minimizes problematic scorching that occurs when the candle holder is in direct contact with the underlying surface. BASC brought suit against Limited Brands, Inc., Bath & Body Works, Inc., and Henri Bendel, Inc. (collectively "Limited") for the sale of a candle tin with a removable cover and four protrusions on the closed end of the candle holder.

"[Under KSR,] the analysis that 'should be made explicit' refers not to the teachings in the prior art of a motivation to combine, but to the court's analysis." Slip op. at 14.

After construing the claims, the district court granted BASC's motion for SJ on infringement. In the same motion, the district court denied Limited's motion for SJ for invalidity based on anticipation and obviousness. Further, the district court declared *sua sponte* that the '969 patent was valid as a matter of law.

On appeal, the Federal Circuit first reviewed the district court's claim construction of the term "to seat," which the district court had determined to mean "to rest on or fit into the cover." While Limited argued that the term "to seat" required engagement between the candle holder and the cover, the Court agreed with the district court's construction. From the plain language of the claims, the Court found that the feet are what cause the candle holder to be seated on the cover. This differentiated the claims from the figures of the '969 patent, which showed the candle holder engaged with the cover. Additionally, the Court noted that the specification illustrates feet both resting on the cover and locking into the recesses in the cover. Accordingly, the Court affirmed the district court's claim construction.

The Federal Circuit next considered the district court's determination that the '969 patent was valid. With regard to obviousness, the sole issue in dispute was whether there was motivation to combine the prior art references. The Court reminded that under *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product

not of innovation but of ordinary skill and common sense.” Slip op. at 11 (alteration in original) (quoting *KSR*, 127 S. Ct. at 1742). As it was undisputed that the prior art disclosed all the limitations of the claims, the problem of scorching was well known in the art, and the level of skill in the art was that of an ordinary layman of average intelligence, the Court concluded that the solution, i.e., the claimed invention, was entirely predictable and grounded in common sense. As such, the Court concluded that claims 1 and 5 were obvious under § 103.

The Court further found error in the district court’s determination that *KSR* requires an explicit motivation to combine from the references. The Court clarified that it is the court’s analysis that should be made explicit and not any teaching in the prior art of a motivation to combine. Accordingly, the Court reversed the district court’s SJ on validity and remanded with instruction to grant SJ invalidating claims 1 and 5 of the ’969 patent.

Finally, the Federal Circuit overturned the district court’s grant of SJ of infringement. Specifically, the Court held that it was improper to find infringement of the claims where the accused product was only “reasonably capable” of being configured in such a way that would meet the claim limitations. *Id.* at 16. While case law supports infringement where a product is reasonably capable of meeting the claim limitation, the Court recognized that such cases are limited to claim language that specifies that the claim is drawn to a capability. In contrast, the ’969 patent claims specify that infringement only occurs if the accused product is configured with the cover being used as a base underneath a candle holder with feet. Since there were no facts indicating the accused device necessarily has to be placed in the infringing configuration, the Court overturned the grant of SJ of infringement.

Ninth Circuit Law Limits Scope of False Advertising Claims Under the Lanham Act

Monica Riva Talley

Judges: Lourie (author), Rader, Linn

[Appealed from W.D. Wash., Judge Pechman]

In *Baden Sports, Inc. v. Molten USA, Inc.*, Nos. 08-1216, -1246 (Fed. Cir. Feb. 13, 2009), the Federal Circuit reversed the district court’s denial of

JMOL on Lanham Act claims. The Court concluded that a false advertising claim under section 43(a)(1)(A) and (B) of the Lanham Act, based on use of the term “innovative,” is precluded because this term relates to neither the origin of the goods nor the nature, characteristics, or qualities of the goods.

Both Baden Sports, Inc. (“Baden”) and Molten USA, Inc. (“Molten”) sell high-end basketballs. Baden owns U.S. Patent No. 5,636,835 (“the ’835 patent”), which is directed to a ball with “raised seams” and a “layer of padding underneath the outer covering.” Baden sued Molten for patent infringement and false advertising under section 43 of the Lanham Act, based on Molten’s sale of basketballs allegedly containing Baden’s proprietary technology, and the advertising associated with these balls.

The district court granted Baden’s motion for SJ of patent infringement, finding Molten infringed Baden’s patent regarding the proprietary “dual-cushion technology” used in the parties’ competing basketballs. The district court granted-in-part and denied-in-part Molten’s motion for SJ on the false advertising claims. First, the district court granted the motion based on advertisements that used the terms “proprietary” and “exclusive” because it found that those terms conveyed the idea that Molten invented and owns the basketball technology, and thus was precluded from Lanham Act liability under the Supreme Court’s decision in *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003). The district court, however, denied Molten’s motion for SJ based on advertisements that use the word “innovative,” reasoning that “innovative” does not necessarily connote the inventor of the technology and can describe basketball characteristics, which are subject to Lanham Act liability in light of *Dastar*.

The parties proceeded to trial on damages for patent infringement and on Baden’s false advertising claims based on Molten’s use of the term “innovative” in its advertisements for basketballs utilizing Baden’s patented technology, which Baden claimed falsely implied that the dual-cushion technology was a Molten innovation.

After trial, the district court enjoined Molten from further infringing the ’835 patent in the United States and from stating in its U.S. advertising that dual-cushion technology is “innovative.” Molten moved for JMOL on Baden’s false advertising claims, arguing that *Dastar* precluded Lanham Act claims based on authorship of an idea. The district court denied the motion.

On appeal, Molten argued that the district court erred by failing to dismiss Baden's Lanham Act claim in light of the Supreme Court's holding in *Dastar*. Molten also claimed that the district court erred in excluding evidence relevant to the element of falsity regarding the "innovation" language in its advertisements, and that the jury's \$8M damages award for patent infringement was excessive.

"We agree with Molten that *Dastar* precludes Baden's section 43(a) claim. The Supreme Court stated in *Dastar* that section 43(a) of the Lanham Act does not have boundless application as a remedy for unfair trade practices. Because of its inherently limited wording, section 43(a) can never be a federal codification of the overall law of unfair competition, but can only apply to certain unfair trade practices prohibited by its text. Section 43(a) of the Lanham Act does not create liability from Molten's advertisements because those advertisements do not concern the 'origin of goods,' to which section 43(a)(1)(A) is directed, nor do they concern the 'nature, characteristics, [or] qualities' of the goods, which is what Ninth Circuit law has interpreted Section 43(a)(1)(B) to address." Slip op. at 7 (alteration in original) (citation omitted).

Applying Ninth Circuit law, the Federal Circuit first considered Baden's section 43(a) Lanham Act claim and agreed with Molten that *Dastar* does preclude Baden's false advertising claim. The Federal Circuit reminded that the Supreme Court in *Dastar* held that "origin of goods," as that term is used in section 43(a), does not refer to "the person or entity that originated the ideas or communications that 'goods' embody or contain." Slip op. at 8 (quoting *Dastar*, 539 U.S. at 32). Instead, the Supreme Court read "origin of goods" as referring "to the producer of the tangible goods that are offered for sale, and not to the author of any idea, concept, or communication embodied in those goods." *Id.* at 8-9 (quoting *Dastar*, 539 U.S. at 37). Because *Dastar* Corporation ("Dastar") was the "origin," or producer, of the products it sold, the Supreme Court held that *Dastar* was not liable for false advertising under the Lanham Act. Because of its inherently limited wording, the *Dastar* court noted that section 43(a) can never be a federal codification of the overall law of unfair competition, but can only apply to certain unfair trade practices prohibited by its text.

The Federal Circuit then evaluated whether Molten's advertising refers to the "producer of the tangible goods," in which case a claim under section 43(a)(1)(A) would be proper, or whether it refers to "the author of" the idea or concept behind Molten's basketballs, in which case the claim would be foreclosed by *Dastar*. *Id.* at 9. The Court found that *Dastar* does not permit Baden to claim false advertising under section 43(a)(1)(A) because Baden did not argue that someone other than Molten produces the infringing basketballs, and nothing in the record indicated that Molten is not in fact the producer of the balls. Thus, the Court concluded that Baden's claims are not actionable under section 43(a)(1)(A) because they do not "cause confusion . . . as to the origin" of the basketballs. *Id.* (alteration in original).

The Court then explained that section 43(a)(1)(B) also does not apply to Baden's claims, as the Ninth Circuit does not interpret this section to apply to false designation of authorship. The Court noted that, following the Ninth Circuit's interpretation of section 43(a)(1)(B) in *Sybersound Records, Inc. v. UAV Corp.*, 517 F.3d 1137, 1144 (9th Cir. 2008), to read the section otherwise would create an overlap between the Lanham and Patent acts. Section 43(a)(1)(B) applies to the characteristics of the goods, the Court explained, and authorship is not a nature, characteristic, or quality of the goods as those terms are used in section 43(a)(1)(B).

The Court concluded that Baden had alleged nothing more than false designation of authorship because no physical or functional attributes of the basketballs are implied by Molten's advertisements. In the Court's view, the term "innovative" only indicates, at most, that its manufacturer created something new, or that the product is new, irrespective of who created it. Thus, the Court concluded that Baden could not avoid the holding in *Dastar* by framing a claim based on false attribution of authorship as a misrepresentation of the nature, characteristics, and qualities of a good.

The Court rejected Baden's argument that there was sufficient "non-*Dastar*" evidence at trial to independently support the jury's Lanham Act award. Specifically, Baden pointed to Molten's "switch" to a nondual-cushion design while still advertising their basketballs as containing dual-cushion technology and Molten's false claims that its basketballs were designed by a prominent Italian designer. Because the Court found that Baden did not pursue these false advertising arguments at trial, the Court refused to consider them on appeal. Accordingly, the Federal Circuit reversed the district court's denial of JMOL on Baden's Lanham Act claims.

The Federal Circuit also refused to consider as moot Molten's arguments that the district court erred in excluding evidence relevant to the element of falsity regarding the "innovation" language in its advertisements and that the \$8M damages award for patent infringement was excessive.

The Court did consider, however, Baden's cross-appeal based on patent law, in which Baden argued that, absent an injunction, there is a substantial likelihood of customer confusion about the basketballs. The Court rejected Baden's argument that the district court erred by not applying the Lanham Act standard to its injunction ruling because the Court found that Baden's request for an injunction was brought under the Patent Act. The Court refused to allow Baden to argue a new statutory basis for its injunction on appeal. Further, because the injunction requires Molten to "inform consumers that Molten basketballs employing 'dual-cushion' technology are not available in the United States," the Court concluded that no potential consumer confusion exists. Slip op. at 15-16.

Covenant Not to Sue for Past Infringement Did Not Divest District Court of Jurisdiction of Declaratory Counterclaims Applicable to Future Infringement

Anita Bhushan

Judges: Newman (author), Schall, Moore

[Appealed from C.D. Cal., Judge Gutierrez]

In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, No. 08-1050 (Fed. Cir. Feb. 13, 2009), the Federal Circuit reversed and remanded the district court's dismissal of an accused infringer's counterclaims of invalidity and unenforceability for lack of jurisdiction under Fed. R. Civ. P. 12(b)(1) and for lack of an actual case or controversy.

Revolution Eyewear, Inc. ("Revolution") owns U.S. Patent No. 6,550,913 ("the '913 patent"), directed to magnetically attached auxiliary eyeglasses. In 2003, Revolution sued Aspex Eyewear, Inc. ("Aspex") for infringement of the '913 patent. Aspex stopped selling the allegedly infringing eyewear after the suit was filed, and filed counterclaims for noninfringement, invalidity, and unenforceability of the '913 patent in responding to the complaint.

During pretrial proceedings, the district court granted Aspex's motion for SJ on the invalidity counterclaim, dismissed the other counterclaims as moot, and entered final judgment of invalidity. Revolution appealed, and the Federal Circuit vacated the judgment of invalidity and remanded in light of claim construction issues. Shortly thereafter, the district court awarded attorneys' fees to Aspex under 35 U.S.C. § 285. Revolution appealed, but the Federal Circuit dismissed for lack of final judgment based on the previous remand. On remand, the district court set a trial date for invalidity and unenforceability.

Just before trial, Revolution unconditionally covenanted not to sue Aspex for infringement of the '913 patent "based upon any activities and/or products made, used, or sold on or before the dismissal of this action." Slip op. at 3. Revolution filed this covenant, along with a motion to dismiss its infringement suit under Fed. R. Civ. P. 41(a)(2)

and a motion to dismiss Aspex's counterclaims for lack of jurisdiction under Fed. R. Civ. P. 12(b)(1), and for absence of the constitutionally required case or controversy. Aspex objected to the motion to dismiss its counterclaims, arguing that an actual controversy continued to exist because Revolution's covenant applied only to past infringement.

"This case is of larger substance than merely a would-be competitor seeking to test the waters by way of an advisory judicial opinion on an adverse patent," Slip op. at 9.

The district court dismissed the claims and counterclaims because, as Revolution covenanted not to sue in the future for products made, used, or sold in the past and the present, any actual controversy in the present had been removed from the case. Accordingly, the district court held that it no longer had subject matter jurisdiction over the counterclaims. Aspex appealed the dismissal of its counterclaims.

On appeal, the Federal Circuit agreed with Aspex that the undisputed fact that the covenant not to sue would not protect Aspex from suit if Aspex engaged in future marketing of the accused eyewear constituted a critical distinction from the Court's earlier decision in *Super Sack Manufacturing Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995). There, the Federal Circuit held that, where a covenant not to sue only applied to products as they existed at the time of the suit even if made and sold in the future, whether any unknown future products of changed structure would be sufficiently at risk of infringement was too speculative an issue to warrant present prosecution of declaratory charges of invalidity. In contrast, the Court reasoned that in this case, Aspex stated that it did not intend to change its design of the accused product, and the covenant did not extend to future sales of the same structure.

The Federal Circuit next turned to *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In *MedImmune*, the Supreme Court held that a DJ action is available when the facts as alleged "under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Slip op. at 5 (quoting *MedImmune*, 549 U.S. at 127). The Federal Circuit agreed with the district court that

MedImmune did not change the well-established rule, as enunciated in *Super Sack*, that an actual controversy must exist at all stages of judicial review, not merely when a complaint is filed. The Court, however, acknowledged that *MedImmune* imposed a totality-of-the-circumstances test.

The Federal Circuit also surveyed its own case law. The Court began by noting that "[w]hether a covenant not to sue will divest the trial court of jurisdiction depends on what is covered by the covenant." *Id.* at 6. The Court first considered *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007), where it explained that DJ jurisdiction is met when the patentee "puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." Slip op. at 6 (quoting *SanDisk*, 480 F.3d at 1381). The Court in *SanDisk* held that when a party's proposed activity resulted in an assertion of legal rights by the patentee, the party needs to actually infringe before seeking a declaration of rights.

The Federal Circuit next considered *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007), a post-*MedImmune* case in which DJ jurisdiction was found not to exist. In *Benitec*, the patentee filed a covenant not to sue a competitor for infringement based on the competitor's development of a drug product that federal approval had not yet been applied for. The competitor wished to continue to challenge the patent, but the district court found no actual controversy existed because the competitor was exempt from liability for infringement due to the Hatch-Waxman Act. The Federal Circuit held that, based on the entirety of the circumstances, there was no actual controversy because the possibility of a future infringement suit based on future acts was too speculative.

The Federal Circuit distinguished Revolution's covenant from the one in *Benitec*, noting that there, as in *Super Sack*, the continuing activities of the would-be infringer were not subject to an infringement suit, either because of a statutory exemption or because of a covenant that extended to future production and sale of the same products that were the subjects of the infringement suit. Accordingly, there was no reasonable apprehension of suit in either *Benitec* or *Super Sack*. By contrast, Revolution's covenant did not extend to future sales of the same products that had been sold before.

The Federal Circuit further reasoned that *MedImmune* made clear that "[t]he rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested

legal rights finds no support in Article III.” Slip op. at 8 (quoting *MedImmune*, 549 U.S. at 134). The Court noted that Revolution was proposing that, for a justiciable controversy to exist, Aspex would have to manufacture and sell the accused eyewear before challenging the ‘913 patent and risk being held a willful infringer subject to treble damages. Thus, the Federal Circuit concluded that *MedImmune* counseled a thoughtful review of the entirety of the circumstances in this case.

Turning to the present appeal, the Court found that the *MedImmune* requirements for DJ jurisdiction were satisfied. The Court first noted that Aspex maintained that it had the right to make the products at issue because the ‘913 patent was invalid and unenforceable. Moreover, Aspex’s planned activity was not speculative—Aspex appeared to have the accused product in storage and wished to sell it again. Finally, the Court noted that Revolution stated in oral argument that it would return to court if Aspex reentered the market with the accused products. Thus, applying the *MedImmune* factors, the Federal Circuit concluded that the dispute was definite and concrete because it pertained to the ‘913 patent as applied to the product Aspex previously produced and sold and wished to produce and sell again. The dispute was real and substantial, as evinced by the lengthy litigation and the limited covenant. The issue “touch[ed] the legal relations of parties having adverse legal interest” because it affected whether Aspex could return to the market without risking treble damages. Slip op. at 9. Finally, the Court reasoned that the dispute was amenable to “specific relief through a decree of a conclusive character” because the resolution of the counterclaims for invalidity and unenforceability of the ‘913 patent would conclusively determine the issue. *Id.*

The Court rejected Revolution’s suggestion that the case presented a request for an advisory judicial opinion. The Federal Circuit reasoned that the parties had already been in infringement litigation initiated by the patentee, the case had been pending since 2003, the case already produced an SJ of invalidity, and the covenant was filed in 2007 after four years of litigation and just before the trial on enforceability. Moreover, throughout this period, Aspex removed the accused eyewear from the market, yet Aspex would not be shielded by the covenant if it now returned the product to the market. Under these circumstances, the Court concluded that Aspex’s declaratory action met *MedImmune*’s requirement of “sufficient immediacy and reality.” *Id.*

Finally, the Court concluded that the district court cases Revolution cited supported the conclusion that

DJ jurisdiction for Aspex’s counterclaims existed. The Court noted that in all of the cases, no continuing case or controversy was found because the covenants covered the current products whether they were sold before or after the covenant. In contrast, Revolution did not offer a covenant on the current products in this case, opting to retain the right to sue for future infringement. The Court noted that by retaining this right, Revolution preserved the controversy to a level of “sufficient immediacy and reality” to allow Aspex to pursue its DJ counterclaims. Accordingly, the Court held that there was an actual controversy within the meaning of the DJ Act and reversed the district court’s dismissal, remanding the case for further proceedings.

No Inequitable Conduct for Failing to Investigate and Disclose to the PTO a Competitor’s Unsubstantiated Claim of Prior Art

Melanie R. Grover

Judges: Rader (author), Friedman, Bryson

[Appealed from D.N.J., Judge Brown]

In *Rothman v. Target Corp.*, No. 08-1375 (Fed. Cir. Feb. 13, 2009), the Federal Circuit affirmed-in-part and reversed-in-part the district court’s denial of plaintiff Rothman’s JMOL motions. The Court affirmed the denial of JMOL for invalidity but reversed the denial of JMOL for unenforceability due to inequitable conduct.

U.S. Patent No. 6,855,029 (“the ‘029 patent”) claims a nursing garment with a built-in nursing bra. After spending a few days thinking about the idea, Ms. Rothman created a prototype in one day by combining an off-the-shelf tank top, an off-the-shelf nursing bra, additional fabric, and fasteners. Thereafter, Ms. Rothman filed for a patent application and, during its prosecution, formed Glamourmom LLC (“Glamourmom”) to produce, market, and sell the invention. After licensing negotiations with defendant Leading Lady broke down, Glamourmom brought an infringement suit a few months after the ‘029 patent issued.

A jury found the ‘029 patent infringed by all but one defendant, but they also found the patent anticipated, obvious, and unenforceable due to inequitable conduct. After trial, Glamourmom renewed its JMOL motions that the patent-in-suit was not anticipated, not obvious, infringed by all defendants, and not

unenforceable for inequitable conduct. The district court denied all of Glamourmom's JMOL motions and awarded costs to the defendants.

**“Receipt of threatening letters containing vague descriptions of unsubstantiated prior art at the tail end of a souring business relationship does not create an automatic duty of disclosure.”
Slip op. at 27.**

On appeal, the Federal Circuit found the jury's verdict on obviousness supported by substantial evidence, rejecting all three of Glamourmom's arguments in support of nonobviousness. First, the Court disagreed with Glamourmom's argument that the testimony from the defendants' expert and the defendants themselves showed the garment was not obvious. The expert testified that the idea to combine a tank top with a nursing bra did not occur to him and was not imaginable in his work. The Court explained that an expert's testimony regarding his own inventive feats has little relevance to whether an invention would have been obvious to a person of ordinary skill in the art, and therefore a reasonable jury could dismiss this testimony. In addition, the Court stated that nothing in defendants' own testimony motivated the Court to question the jury's verdict because the testifying defendants were not experts or ordinary nursing garment artisans, and, even if they were, the jury could properly credit or discredit their testimony.

The Federal Circuit also did not agree with Glamourmom's second argument that the defendants had failed to show a motivation to combine the prior art elements. The Court explained that the invention was in a very predictable field, and in such a field, a trial record may more readily show a motivation to combine known elements to yield a predictable result. The Court concluded that the defendants presented ample testimony supporting a motivation to combine.

Finally, the Court disagreed with Glamourmom's last argument that the jury failed to properly consider secondary indicia of nonobviousness. The Court reiterated that a strong prima facie obviousness showing may stand even in the face of considerable evidence of secondary considerations, and that evidence of secondary considerations is a factual

component within the province of the jury. The Court further explained that because the district court had correctly instructed the jury to consider and weigh the evidence of secondary considerations, there was no reason to disturb the jury's verdict.

Because the Court held the district court had properly denied the JMOL motion for obviousness, it declined to address the additional validity and infringement arguments made by Glamourmom. The Court then turned to the issue of inequitable conduct, considering the two counts brought at trial.

The first count alleged that Glamourmom failed to submit two known prior art references, owned by defendant Leading Lady, to the PTO. The Court held no reasonable jury could find the first prior art reference material to a reasonable examiner because the art was cumulative of, and less material than, other references already disclosed to the PTO by the patentee. Because it was not material, the Court found that failure to submit this piece of prior art could not support a finding of inequitable conduct.

The Court also found no inequitable conduct in the failure to submit the second piece of prior art to the PTO because no reasonable jury could find an intent to deceive the PTO. After a year of licensing negotiations, Leading Lady informed Glamourmom in a letter that they were going to sell their own prior art nursing top, style 460, to Target instead of Glamourmom's top. No sample, photograph, drawing, or description of the style 460 top was sent to Glamourmom with the letter. The Court held that receipt of a threatening letter containing vague descriptions of unsubstantiated prior art at the end of a souring business relationship neither creates an automatic duty to disclose the prior art nor creates a duty to further investigate the declaration that the reference is in fact prior art. Because Glamourmom had nothing more than a vague description of the prior art, the Court reasoned, Glamourmom could not be charged with culpable intent in withholding information it did not have.

The Court further pointed out that Glamourmom had grounds for a good-faith belief that style 460 was not material prior art; a patent application for style 460 listed the '029 patent as prior art, and Leading Lady's claimed invention date occurred two years after the invention of the '029 patent top. In addition, the Court pointed out the existence of style 460 was disclosed to the PTO when Glamourmom filed a Petition to Make Special. As part of the Petition, Glamourmom submitted the letters from Leading Lady discussing both pieces of prior art. Based on these findings, the Court stated there was no intent

to deceive the PTO, and therefore no inequitable conduct.

The second count of inequitable conduct alleged that Glamourmom's patent attorney made unsubstantiated statements about how one of ordinary skill in the nursing bra field would interpret certain prior art references. Glamourmom's attorney argued to the examiner that nursing garments and maternity garments were not analogous and it was therefore improper to combine a prior art reference from nursing garments with prior art from garments generally. The Court pointed out that the law prohibits genuine misrepresentations of material fact, but prosecuting attorneys are free to present arguments in favor of patentability without fear of committing inequitable conduct. Holding that the statements in this case were attorney argument attempting to characterize the prior art in a manner favorable to the attorney's client, the Court found no reasonable jury could rely on this statement for clear and convincing proof of inequitable conduct. Without substantial evidence to support any of the claims of inequitable conduct, the Court reversed the jury's verdict on this point and vacated the award of attorneys' fees.

Statutory Thirty-Month Stay May Be Extended Based on a Party's Uncooperative Discovery Practices

Judy W. Chung

Judges: Michel, Rader (author), Prost (dissenting)

[Appealed from S.D. Ind., Judge Barker]

In *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, No. 09-1071 (Fed. Cir. Feb. 24, 2009), the Federal Circuit affirmed the district court's extension of the statutory thirty-month stay under 21 U.S.C. § 355(j)(5)(B)(iii) (2003), preventing the FDA from finally approving Teva Pharmaceuticals USA, Inc.'s ("Teva") ANDA.

Eli Lilly and Company ("Lilly") is the manufacturer of FDA approved, Evista® brand raloxifene hydrochloride ("raloxifene") tablets that are used for the treatment and prevention of postmenopausal osteoporosis. In May 2006, Teva filed an ANDA and Lilly subsequently sued Teva for patent infringement. The FDA then stayed approval of Teva's ANDA for thirty months. Thereafter, the district court set a trial date four months after the end of the thirty-month period. Less than two months before the discovery

deadline, Teva amended its ANDA, changing its proposed generic formulation and including a new particle-size measuring methodology. In addition, Teva produced one batch sample before and two batch samples after the discovery deadline. Further, Teva produced 27,000 pages of related documentation after the discovery deadline. Lilly moved the district court to extend the statutory thirty-month stay due to Teva's alleged discovery violations and contended that Teva "fail[ed] to 'reasonably cooperate in expediting the action' . . . as evidenced by Teva's last-minute alteration of its proposed drug product and its 'multiple delays in producing critical discovery . . . [which have] adversely affected Lilly's infringement case and trial preparation.'" Slip op. at 5 (alterations in original). The district court granted the motion to extend the stay until the trial date. Subsequently, Teva filed a motion for an expedited appeal with the Federal Circuit.

On appeal, a panel majority determined that the record contained sufficient evidence to support the order and that the district court did not abuse its discretion in extending the thirty-month stay. In particular, the majority noted that evidence in the record indicated that Teva had altered its proposed generic formulation just eight months before trial, and "then delivered its changed samples to Lilly past the court's . . . discovery deadline." *Id.* at 7. In affirming the district court's extension of the thirty-month stay, the majority distinguished the decision in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002), where the Federal Circuit vacated a district court's decision to shorten the thirty-month stay. In *Andrx*, the Federal Circuit held that the district court had erred by basing its decision on Biovail's "positions before the FDA," instead of determining whether Biovail cooperated in expediting the patent litigation. *Id.* According to the majority, "[u]nlike *Andrx* in this case, the district court extended the statutory thirty-month stay based on its findings of Teva's lack of cooperation in expediting the patent litigation in its court." Slip op. at 9.

In a dissenting opinion, Judge Prost argued that the majority misapplied the standard of review and granted too much deference to the district court in extending the stay. According to Judge Prost, the district court did not make the necessary findings to extend the stay, but merely provided two insufficient justifications for the order: "(1) to provide Lilly 'a sufficient opportunity to identify the nature and composition of [Teva's] raloxifene product . . . , and (2) to give Lilly 'a reasonable amount of time . . . to test and report on [Teva's] altered raloxifene samples . . . in preparation for trial.'" Prost Dissent at 3-4.

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Abbreviations

ALJ Administrative Law Judge
ANDA Abbreviated New Drug Application
APA Administrative Procedures Act
APJ Administrative Patent Judge
Board Board of Patent Appeals and Interferences
Commissioner Commissioner of Patents and Trademarks
CIP Continuation-in-Part
DJ Declaratory Judgment
DOE Doctrine of Equivalents
FDA Food and Drug Administration
IDS Information Disclosure Statement
ITC International Trade Commission
JMOL Judgment as a Matter of Law
MPEP Manual of Patent Examining Procedure
PCT Patent Cooperation Treaty
PTO United States Patent and Trademark Office
SJ Summary Judgment
TTAB Trademark Trial and Appeal Board

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Looking Ahead

The U.S. Supreme Court has received numerous amicus briefs supporting the petition for a writ of certiorari filed in *Bilski v. Doll*, No. 08-1964. Included among the amici curiae were intellectual property law associations, law professors, solo patent practitioners, and several companies representing a wide range of industries, including software, biotechnology, and business consulting. Some overarching themes from the amicus briefs include arguments that the Federal Circuit's machine-or-transformation test outlined in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), runs counter to Supreme Court precedent, stifles innovation, and is too rigid (similar to the teaching-suggestion-motivation rule that was rejected by the Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)). The PTO's brief and oppositions to the petition are due in April. Look for further updates on this petition in the months ahead.